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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Barbro Hemmendorff

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 02/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,023

Applicant(s)

HEMMENDORFF ET AL.

Examiner

Suryaprabha Chunduru

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,8,12,15,18,19,21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,8,12,15,18,19,21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status

1. The current application was returned by the BPAI after an affirmance in part decision. The decision indicated that claims 1-3, 6-7, 11, 13-14, 16-17, 20 in Groups I and II were affirmed over Builder et al., claims 5, 15 and 22 are vacated in view of Builder et al. and claims 8, 12, 18-19, 21 were reversed under 35 USC 102(e). Claims 1-3, 5-8, 11-22 were appealed. So rejections regarding claims 1-3, 6-7, 11, 13-14, 16-17, 20 were affirmed and these claims are closed for further prosecution, in accordance with MPEP 1214.06(III) and the previous grounds of rejection are maintained as affirmed by the BPAI and not appealed to the Federal Circuit.
2. Claims 5, 8, 12, 15, 18-19, 21-22 represent claims which were not in rejections affirmed by the BPAI. These claims will therefore be treated below. In order to simplify prosecution, the claims will be treated as independent and include all the limitations of the broadest independent claim from which they depend for purposes of the prior art rejections.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 15, 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As suggested by the Board on page 7 of the Board decision, Claims 5, 15 and 22 are indefinite and unclear in the light of the specification. The instant claims recite 'pH is equal to or lower than pH 7. The meets and bounds of the claims are unclear in the light of the specification

because the instant specification discloses several pH adjustments of the cell concentrates of the culture medium above pH 7.0 (see at least examples 1-4) which do not fall within the scope of the instant claim limitations. Thus it is unclear to which process step, the claimed pH limitations would meet.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5, 8, 12, 15, 18-19, 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Builder et al. (USPN. 5,663,304).

Builder et al. teach a method of claims 5, 8, 12, 15, 18-19, 21-22 for production of recombinant peptides comprising fermenting cells (host cells) to produce recombinant peptides in the presence of metal salt (alkali metal salt) prior to peptide isolation (see column 26, lines 34-67, column 27, 1-67, column 28, lines 15-33, column 6, lines 42-67, and column 7, lines 1-9).

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Builder also teach that (i) the use of metals facilitate disulfide oxidation of polypeptides and yield correct refolding of a misfolded polypeptide contained in host cells (see column 6, lines 42-60); metal salts include sodium chloride, potassium chloride, sodium phosphate, potassium phosphate (see column 28, lines 15-33, column 11, lines 42-54);

With regard to claims 5, 15, 22, Builder et al. teach that alkali metal salt buffer (pH 10.5) was added after fermentation and pH was adjusted to 3.5 with phosphoric acid (see column 28, lines 28-33 and column 16, lines 47-55);

With regard to claims 8, 12, 18-19, 21, Builder et al. teach that the method includes human growth hormone as a preferred mammalian polypeptide (see column 9, lines 11-18).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify or substitute the method of producing a recombinant polypeptide as taught by Builder et al. with the step of producing a recombinant human growth hormone to achieve expected advantage of developing a method for manufacturing human growth hormone. An ordinary skill in the art would have reasonable expectation of success that the method would work as suggested by Builder et al. because Builder et al. have explicitly indicated that human growth hormone is a particularly preferred mammalian polypeptide according to their method (col. 9, line 11-20). Therefore an ordinary practitioner would have been motivated to modify the method of Builder et al. with the inclusion of the step of producing human growth hormone for the purpose of developing a method for production of human growth hormone, such modification of the method is considered functionally equivalent to the claimed method in the absence of secondary considerations.

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Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Suryaprabha Chunduru
Examiner
Art Unit 1637


JEFFREY FREDMAN
PRIMARY EXAMINER



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